

Application No. 10/619,766
Attorney Docket No. PR60153US

REMARKS / ARGUMENTS

Introductory Comments

Applicants thank Examiner David P. Stitzel for the thorough examination of the present application. Claims 1-8, 11-18 and 61-63 are pending in the present application. Claims 1 and 17 have been amended to better define the present invention. Features recited by Claim 8 have been incorporated into Claim 1. Claims 9-10 and 19-60 have been canceled without prejudice to future prosecution. Claims 61-63 are new and set forth additionally patentable subject matter. All features recited by these claims are fully supported by the specification. In view of the amendments and remarks set forth herein, reconsideration, a withdrawal of all rejections, and a Notice of Allowance are respectfully solicited.

35 U.S.C. § 102

Claims 1-5 and 36-39 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,365,196 to Venkatesh et al. ("Venkatesh"). Applicants respectfully traverse each and every aspect of this rejection.

Venkatesh does not anticipate the claims in question because it does not clearly disclose each and every feature recited by such claims. Venkatesh does not disclose compositions and/or dosage forms employing dissolution rate stabilizer in the amounts as recited by these claims. Accordingly, a withdrawal of this rejection is respectfully solicited.

35 U.S.C. § 103

Claims 8-10, 30-32, 40-46, 49-53 and 57-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Venkatesh in view of U.S. Patent No. 5,425,950 to Dandiker et al. ("Dandiker"). Applicants respectfully traverse each and every aspect of this rejection.

As stated above, Venkatesh does not disclose or remotely suggest employing dissolution rate stabilizer in the levels recited by the pending claims. Dandiker does not address the deficiencies of Venkatesh, and does not render these claims obvious in

Application No. 10/619,766
Attorney Docket No. PR60153US

combination with Venkatesh . At best, Dandiker merely recites that sodium carboxymethylcellulose can be used in pharmaceutical composition as an excipient, i.e., disintegrant. No specific teaching is given as to the amounts which this specific component can be employed .

In this obviousness rejection, the Office alleges:

.... [T]he Dandiker '950 patent teaches the interchangeability of sodium carboxymethylcellulose with microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxypropylcellulose as a disintegrant, filler and/or binder (column 5, lines 59-62; column 6, lines 15-32)"

Assuming this statement to be correct, Applicants submit that Dandiker teaches away from the claimed invention as now recited. If one assumes that indeed sodium carboxymethylcellulose as an example of a dissolution rate stabilizer is interchangeable with the other ingredients, then Dandiker teaches using such a component in amounts that far exceed the amounts set forth in the present claims. On this point, and for convenience, Applicants refer the Office to Appendix I attached herewith. Appendix I lists amounts of components that the Office alleges are interchangeable with sodium carboxymethylcellulose and their corresponding location within the specification of Dandiker. As shown , a person of ordinary skill in the art clearly would not look to the teachings of Dandiker when considering employing a dissolution rate stabilizer (e.g., sodium carboxymethylcellulose) as recited by the claimed invention. Moreover, Dandiker does not even disclose formulations of lithium carbonate.

The present invention offers a significant contribution to the art. By using a relatively lower amount of rate dissolution stabilizer (e.g., sodium carboxymethylcellulose) in a lithium carbonate pharmaceutical composition, an enhanced dissolution profile is capable of being achieved, and thus is very advantageous to the patient. Such a composition is not taught or suggested by the prior art. A withdrawal of this rejection is respectfully solicited.

Various other obviousness rejections are made by the Office in the present Action. Claims 11-16 are rejected under 35 U.S.C. § 103(a) over Venkatesh in view of U.S. Patent No. 4,346,709 to Schmitt ("Schmitt"). Claims 17-18 and 23 are rejected

Application No. 10/619,766
Attorney Docket No. PR60153US

under 35 U.S.C. § 103(a) over Venkatesh in view of Dandiker and further in view of Schmitt. Claims 6-7 and 47-48 are rejected under 35 U.S.C. § 103(a) over Venkatesh in view of U.S. Patent Publication No. 2002/0056206 ("the '206 Publication"). Applicants respectfully traverse each and every aspect of these rejections. Neither Schmitt nor the '206 Publication address the deficiencies of Dandiker in that they do not teach or suggest lithium carbonate compositions employing sodium carboxymethylcellulose in the matter recited by the present claims. Schmitt teaches erodible devices having a body which contains a poly(orthoester) or poly(orthocarbonate) presumably to aid in the rate of erosion. The '206 Publication teaches a spray drying process for the preparation of pharmaceutical compositions containing small particles of phospholipids-stabilized fenofibrate. Accordingly, withdrawal of these rejections is respectfully solicited by Applicants.

The points of the Office Action being addressed in full, a Notice of Allowance is respectfully solicited.

Respectfully submitted,



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Enclosure: Appendix I

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